

## **Remarks**

As stated above, the applicants appreciate the Examiner's thorough examination of the subject application and request reexamination and reconsideration of the subject application in view of the preceding amendments and the following remarks.

Currently, claims 1-20 are pending in the subject application, of which claims 1, 12 & 17 are independent claims and claims 2-11, 13-16 and 18-20 are dependent claims. Claims 1, 6, 8, 9, 12-13 and 16-17 have been amended and claim 7 has been cancelled. Each amendment is supported within the specification as originally filed and applicants respectfully assert that no new matter has been presented by any amendments herein.

Concerning Item 2 of the subject action, the Examiner objects to claims 1, 12 & 17 due to their inclusion of "therebetween". While the applicants truly believe and respectfully assert that the use of "therebetween" is proper within claims 1, 12 & 17, in order to facilitate prosecution, applicants have amended claims 1, 12 & 17 to replace "therebetween" with "between". Applicants respectfully assert that these amendments adequately address this objection.

Concerning Items 3-5 of the subject action, claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of the teachings of Whatley et al (U.S. Patent No. 6,452,158 B1; hereinafter Whatley) and Shearn (U.S. Patent No. 6,645,177 B1; hereinafter Shearn).

Applicants claim (in currently amended claim 1):

1. (Currently Amended) A displacement sensor for a substance dispensing device having a reservoir and a translating piston, the sensor comprising: a plunger rod coupled to the piston bearing an encoded pattern of encoding features, the spacing of the encoding features from one another defining spaces between such that any two adjacent spaces form a unique sequence; a light source for

illuminating the encoded pattern; a detector array for detecting light from the illuminated encoded pattern and generating a detector signal; and a processor for determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal, *wherein the encoding features further uniquely identify a characteristic of the reservoir other than the displacement of the plunger rod.*

Applicants claim (in currently amended claim 12):

12. (Currently Amended) A dispensing apparatus comprising: a reservoir having a cylindrical inner volume for containing a substance; a plunger rod for impelling a piston along a linear axis of motion within the inner volume of the reservoir in order to displace and dispense a measured quantity of the substance; an encoding pattern of encoding features disposed along the plunger rod in a direction parallel to the linear axis of motion of the piston, the spacing of the encoding features from one another defining spaces between such that any two adjacent spaces form a unique sequence; an illumination source for illuminating the encoded pattern; a detector array for detecting light from the illuminated encoded pattern and generating a detector signal; and a processor for determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal, *wherein the encoding features further uniquely identify a characteristic of the reservoir other than the displacement of the plunger rod.*

Applicants claim (in currently amended claim 17):

17. (Currently Amended) A method for measuring a rate of dispensing a substance by means of a dispenser having a piston driven along an axis of motion within a reservoir of the substance, the method comprising: illuminating with an illumination source an encoded pattern of encoding features disposed upon a plunger rod coupled to the piston, the spacing of the encoding features from one another defining spaces between such that any two adjacent spaces form a unique sequence; detecting light from the illuminated encoding features and generating a detector signal; and determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal, *wherein the encoding features further uniquely identify a characteristic of the reservoir other than the displacement of the plunger rod.*

Applicants have amended each of independent claims 1, 12 & 17 to include subject matter that defines the encoded features as uniquely identifying a characteristic of the reservoir other than the displacement of the plunger rod. Applicants have also amended dependent claim 6 for consistency with amended claim 1 and amended dependent claims 8 & 9 for consistency with

dependent claim 6. Further, applicants have amended dependent claims 13 & 16 to correct typographical errors.

Due to the amendment of independent claims 1, 12 & 17, all pending claims now require that “the encoding features further uniquely identify a characteristic of the reservoir other than the displacement of the plunger rod”. Support for this feature is found in the specification of the subject application at least at Paragraph 29 as published. Specifically, the subject application discloses the following:

The three versions of slot spacings, given in inches in Table I, meet the preferred criteria discussed in the foregoing paragraph. The spacing of any two adjacent spaces may be coded to uniquely define a version of the reservoir, so that different concentrations of medicinal agent may be supplied and distinguished. Characteristics of the reservoir version that may be identified in this manner include, without limitation, the inner diameter of the reservoir, and the composition (plastic or glass, for example) of the wall of the reservoir. Additionally, the distance between the end of the plunger rod and the last slot may uniquely identify a reservoir version, so that, in case no more than one slot is within the field of view of the image sensor, the reservoir version may be uniquely identified. *See the Subject Application, paragraph 29.*

Upon review of Whatley and Shearn, it becomes readily apparent that neither Whatley nor Shearn disclose a system in which “the encoding features further uniquely identify a characteristic of the reservoir other than the displacement of the plunger rod”.

Concerning the combination of the Whatley and Shearn references, the Examiner states the following:

The device disclosed by Whatley et al would allow for determination of the position at any point along the piston rod, but does not explicitly disclose the spacing of the encoding features defining spaces such that any two adjacent spaces form a unique sequence. However, Shearn discloses a device in which markers (58) are illustrated to have different sizes as part of the encoding device to determine position. The features that would be used to determine position would be the spaces in between markers (58). This would be feasible because marker (60) is part of the opaque portion of arm (56). Markers (58) would then serve as the spacing of the encoding features.

Accordingly, the Examiner relies upon the “markers (58)” of Shearn to “serve as the spacing of the encoding features”. The “markers (58) of Shearn are illustrated below in FIG. 6 of Shearn.

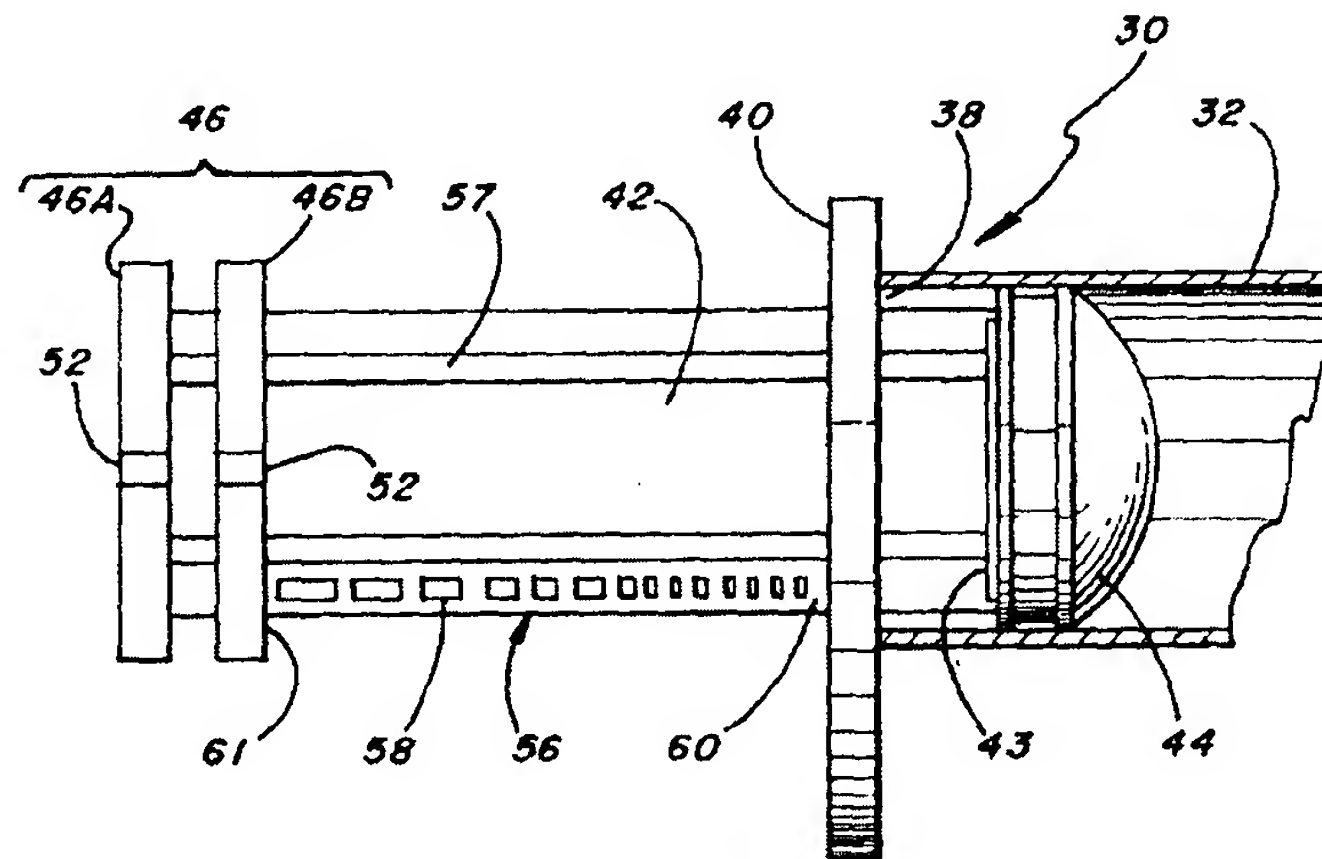


FIG 6

Concerning “markers (58)” of Shearn, Shearn discloses the following:

Referring now to FIG. 6, one of the stem arms of the plunger 42, in this case the nearest arm 56, is provided with a linear grid made up of a series of equally spaced markers 58 along the length of the stem arm. The distal markers 58 at the distal end 60, which in this embodiment is the end nearer the stopper 44, are small in comparison to the markers 58 at the proximal end 61, which in this embodiment is the end nearer the plunger flange 46. *As explained in detail below, these markers 58 serve in detecting linear motion of the syringe and provide an indication of the amount of fluid remaining in the syringe. See Shearn, Column 6, Lines 45-55; Emphasis Added.*

With continuing reference to FIG. 2, the casing 68 is provided with two optoelectronic detectors in this embodiment. The first detector 74 is used to provide detection of linear movement of the syringe plunger and a warning when the near-end-of-infusion (NEOI) point is being reached, i. e., when the syringe is almost empty and needs replacement. The detector 74 is mounted on the casing 68 adjacent the stem arm 56 upon which the markers 58, 60 (FIG. 6) are formed. The detector 74 is of substantially horse-shoe shape, one end of the horse shoe housing a light source and the other end of the horse shoe housing a pair of detectors located alongside one another such that light from the light source is blocked by

the arm 56 so that neither of the detectors are illuminated but, when a marker 58 is positioned between the light source and the detectors, one of the detectors is illuminated. As the syringe plunger travels along the shaft 54, equally spaced dark and light signals are detected by the optoelectronics switch 74. The timing of these signals can be used by a control system to confirm that the plunger is moving at the correct rate. Similarly, a lack of detection of dark and light signals indicates to the syringe driver that no movement of the syringe plunger is occurring. This may be the result of an exhausted syringe, which means that the end of infusion ("EOI") has been reached, thus also providing detection of such condition. The processor of the syringe driver may be programmed to determine the EOI after first detecting the NEOI and to provide an audible and/or visual alarm or other indication of the EOI. *See Shearn, Column 8, Lines 6-32.*

Accordingly, the "markers (58)" of Shearn do not disclose a system in which "the encoding features further uniquely identify a characteristic of the reservoir other than the displacement", as claimed in claims 1, 12 & 17 of the subject application.

Accordingly, applicants respectfully assert that the combination of the teachings of Whatley and Shearn is not a proper basis for a 35 USC §103(a) rejection, as the combination fails to disclose each and every element of the applicants' claimed invention. Therefore, applicants respectfully assert that independent claims 1, 12 & 17 are patentable over the combination of Whatley and Shearn. Further, as dependent claims 2-6, 8-11, 13-16 & 18-20 all depend (either directly or indirectly) upon a patentable base claim, the applicants respectfully assert that dependent claims 2-6, 8-11, 13-16 & 18-20 are also patentable.

In light of the above-described amendments and remarks, applicants respectfully assert that the subject application is now in condition for allowance. No new matter has been added by these amendments. *While the applicants respectfully assert that the subject application is now in condition for allowance, the Examiner is invited to telephone applicants' attorney (@ 617-305-2143) to facilitate / expedite prosecution of this application.* Please apply any charges or credits to deposit account 50-2324.

Respectfully submitted,

26 December 2007

Date

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